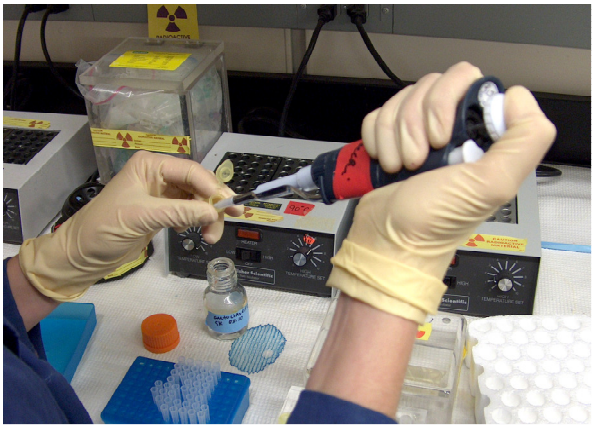

Discovering Rhode Island's Stem Cell Future:

Charting the Course Toward Health and Prosperity

Lieutenant Governor Elizabeth H. Roberts

April 10, 2007

http://www.ltgov.ri.gov

Dear Rhode Islanders,

Last October, I stood with a little girl named Emily Burgess, who suffers from juvenile diabetes, and with Representative James Langevin, and spoke about the hope and promise of stem cell research. I spoke about its potential to improve the lives of those suffering from some of the most destructive diseases of our time, and the congressman and I called on President Bush to loosen restrictions on federal funding of stem cell research.

I also committed to examining the potential for, and the obstacles to, expanding stem cell research in Rhode Island. I am proud to present this report to serve as a stimulus to a vigorous statewide dialogue about the future of stem cell research in our state.

My goal in this report is to educate the reader about the basics of stem cell research and regenerative medicine, what other states are doing and the potential for stem cell research to reduce human suffering and support economic growth in the Ocean State. The report concludes by posing the critical policy questions that I have identified in examining this issue closely. These key policy questions need to be answered and I will work to chart the course for the future of stem cell research in Rhode Island.

In the coming months, I will be working closely with government officials, scientists, researchers, doctors, members of the business community, faculty from our colleges and universities, and concerned members of the public. Working together, we can develop a vision and a plan for the future of stem cell research and regenerative medicine in our state.

We owe it to Emily, to thousands of other Rhode Islanders, and to millions of Americans to move forward with a thoughtful and deliberate discussion of stem cell research and regenerative medicine.

Rhode Island stands at a crossroads when it comes to stem cell research. As a leading advocate for quality health care and quality jobs, I know we must discover our future in biotechnology. I am confident that this report will serve as a foundation for Rhode Island decision-makers to answer the essential policy questions and develop a blueprint for action.

Sincerely,

Elizabeth Roberts

Lieutenant Governor Elizabeth Roberts

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Introduction

Despite remarkable advances in medical science, millions of people each year still suffer from chronic and terminal diseases without effective cures or treatments. Although not a panacea, many scientists are confident that the regenerative therapies that will be developed as stem cell research advances hold tremendous promise to reduce human suffering.

The report presented below is divided into three main sections. The first section is an overview of the science of stem cell research, as well as a summary of the controversy surrounding some aspects of the research. The second section contains information about stem cell research funding at the federal level, and presents a state-by-state review of state-level funding efforts. Finally, the third section lays out the questions that need to be answered before a determination can be made as to how and whether to expand stem cell research and regenerative medicine therapies in Rhode Island.

Section I

The Science of Stem Cells

A. History

Since the beginning of the 20th century, scientists have come to understand that all of the different types of blood and tissue cells in the body develop from what have come to be referred to as "stem cells." According to the National Institute of Health, stem cells have the "remarkable potential to develop into many different cell types in the body."[1] Serving as a sort of repair system for the body, they can theoretically divide without limit to replenish other cells as long as the person or animal is still alive. When a stem cell divides, each new cell has the potential to either remain a stem cell or become another type of cell with a more specialized function, such as a muscle cell, a red blood cell, or a brain cell.[2] This realization has led to some exciting thinking about the possible uses of these undifferentiated cells for growing healthy tissue to replace blood, organs, and tissue damaged by disease or injury. These treatments are generally referred to as regenerative medicine treatments. One regenerative therapy that is already gaining wide application is the use of stem cells drawn from umbilical cord blood that are transplanted into leukemia patients to develop into healthy bone marrow.[3]

Early research into the possible medical uses of stem cells could not advance until scientists could isolate stem cells and manipulate them outside the body. Major breakthroughs were made in 1998 when concurrent research projects headed by University of Wisconsin researcher Dr. James Thomson and Johns Hopkins University researcher Dr. John Gearhart successfully isolated and grew stem cells from human embryos. A year later, researchers began to report that they were able to manipulate stem cells from adult mice in such a way that different tissue types were created.[4] These discoveries laid the groundwork for modern stem cell research.

B. What are stem cells?

The human body is made up of approximately two hundred and twenty different types of cells. Each of these cells has different functions, from the neural cells in the brain that allow us to think, to the cardiac muscle cells in our heart that keep it beating. All of the cells in our bodies developed from stem cells. During the nine months of human pregnancy, our different kinds of functional cells are created when embryonic stem cells differentiate into these various cell types. The embryonic stem cells are the building blocks of

all of the cells that make up the human body. After all of the cell types in our body have been created, along with the tissues and organs that that they form, adult stem cells continue to be produced. Adult stem cells are not as completely flexible to form into all types of special purpose cells as embryonic stem cells are; however, adult stem cells can work to repair damaged or dying cells of their specific type for particular purposes.

What makes stem cells different from all other cells are three properties that they all share: they are unspecialized, they can multiply, and they have the potential to form specialized cells. Unlike specialized cells such as cardiac cells in the heart and stromal cells in connective tissue, stem cells perform no function. They exist solely as the building blocks to develop into specialized cells. Stem cells also have the ability to multiply, and their daughter cells have the potential to either become stem cells, or to differentiate into specialized cells through a process that is not yet fully understood by scientists.[5]

C. Major stem cell types

The two main types of stem cells are adult stem cells and embryonic stem cells. Embryonic and adult stem cells have different characteristics, and research into the potential medical uses of each has strengths and weaknesses. A major advantage of embryonic stem cells is that they are capable of differentiating into all types of body cells, as opposed to adult stem cells that seem to be

My Take

Representative Edith Ajello

"One of the reasons I am so interested in stem cell research is that my father died of Alzheimer's disease, but that is not the only reason. We hear so much about the potential for stem cell research. So whether it is my family, or any family, we need to work to make that potential a reality. Stem cell research has the potential to improve health care and improve quality of life. It is also a great economic development tool in terms of helping institutions of higher education, hospitals, and research facilities."

more limited in terms of which kinds of body cells they can develop into. Embryonic stem cells are also much easier than their adult counterparts to isolate, multiply, and maintain in a laboratory environment. One possible advantage of adult stem cells is that they can potentially be cultivated from patients for use themselves, thereby eliminating any risk of immune rejection of the cells by the body.[6] Adult stem cell research has also provoked a lot of excitement recently in the scientific community; as adult stem cells are found in more and more body tissue, their potential use for transplantation is increasing. Researchers have also been reporting that adult stem cells might have the ability to differentiate a lot more than was previously thought. Many scientists maintain that although there is potential in embryonic stem cell research, adult stem cell research is farther along with regards to clinical uses.[7]

Adult stem cells reside in mature tissue such as bone marrow, blood, and skeletal muscle. Adult stem cells inhabit specific tissue groups and can both renew themselves and differentiate into the specialized cell type of the tissue in which they reside. For example, hematopoietic stem cells are cells that can differentiate into all of the different blood cells, while mesenchymal stem cells can do the same for the cells of the skeleton. Adult stem cells may also have the potential to differentiate into cells of other tissue types, a phenomenon known as transdifferentiation or plasticity.[8]

Embryonic cells used for research are derived from recently conceived embryos, usually between the fourth and seventh day after fertilization. The embryo at this point is in a stage called the blastocyst stage, and consists of an outer layer called a trophoblast, a hollow cavity called a blastocoel, and a group of approximately thirty cells in the middle called the inner cell mass. Researchers create lines of embryonic stem cells by removing the inner cell mass from the blastocyst and transferring it to a laboratory culture dish. The inner cell mass continues to multiply, and as these cells grow they can be transferred onto new culture dishes and used for research purposes. Left to themselves, the embryonic stem cells will begin to group together and spontaneously differentiate into specialized cells; however, scientists have discovered ways to prevent this from occurring and to maintain the newly developing cells in their undifferentiated state. They have also made progress in their efforts to find ways to control how the stem cells differentiate, as well as how to signal to the cells what specialized cells they should differentiate into. The blastocysts used for stem cell research are grown from eggs specifically donated for research and fertilized *in vitro*.[9]

My Take

Congressman James Langevin

"Stem cell research offers the promise of a cure to millions of people who are living with the constant challenges and burdens of chronic diseases and disability. My education on this issue has filled me with tremendous hope, and there is no doubt in my mind that stem cell research is poised to change the face of medicine."

D. Other sources of embryonic stem cells

Many researchers and policymakers are interested in discovering ways of obtaining embryonic stem cells without compromising the embryo from which the cells are drawn. At the end of 2006, researchers at Advanced Cell Technology's laboratory in Worcester, MA, published a paper in the scientific journal *Nature* in which they announced that they had discovered a way to remove embryonic stem cells without harming the developing embryo. The researchers used the methods of a test called pre-implantation genetic diagnosis, in which one cell is removed and tested for abnormalities without harming the embryo. They found that one of these removed cells theoretically has the potential to generate embryonic stem cells. They noted, however, that although their research shows that this can be done in theory, in their actual experiment all embryos were destroyed in the process.[10]

In January 2007, researchers at Wake Forest University and Harvard University announced that they had discovered a new source of stem cells in amniotic fluid. They maintain that these stem cells have many of the same characteristics as embryonic stem cells, and potentially could have the same therapeutic uses. The researchers made clear, however, that they are not sure at this point how many different types of cells can be created from amniotic stem cells, and they stressed that their discovery should in no way be interpreted as meaning that embryonic stem cell research should not continue.[11]

E. Cord blood

Another source of stem cells with already-developed important therapeutic uses is blood from the umbilical cord. Umbilical cord blood, in addition to containing the usual blood cells, is also extremely rich in hematopoietic (blood cell producing) stem cells. Because these stem cells have been differentiated and assigned the task of creating blood cells, they are referred to as "adult" stem cells, even though they are gathered at the time of a baby's birth. This blood can be taken from the cord and attached placenta after the birth of the baby, and therefore can be collected with no risk to either the baby or the mother. It is for this reason that cord blood is being examined and used as an alternative in transplantation to bone marrow to treat such ailments as sickle cell disease and many types of leukemia. Cord blood has an advantage over bone marrow in that it can be transplanted between individuals who are not perfect matches. This makes it especially advantageous to racial and ethnic minorities in the United States, who often have trouble finding perfect bone marrow matches. Cord blood is currently used primarily to treat diseases related to the blood and immune system, but researchers are looking into the possibility that these stem cells might be able to differentiate into other types of cells as well.[12]

Cord blood is currently collected from consenting mothers who either privately bank the blood, or donate it to a public cord blood bank. The American Academy of Pediatrics does not advise private banking unless there is a family history of disease that can be treated with cord blood transplants.[13] Donations made to public cord blood banks are used to treat patients as well as for research purposes.

Despite the fact that collection is simple and the life-saving benefits are enormous, many parents of newborns do not know that cord blood donation is an option. Currently Florida, Illinois, Maryland, New Mexico, Virginia and Wisconsin have laws that require either hospitals or physicians to inform pregnant women and new parents of the option to donate umbilical cord blood. Georgia, Massachusetts, New Jersey, New Mexico, South Dakota and Virginia have all created education and awareness programs to inform the public and doctors about cord blood options.[14]

F. What is the potential of stem cell research?

Stem cell research is still very much in its infancy, and a number of technical hurdles must be overcome before the full potential of research and therapeutic use can be realized. In spite of these challenges, scientists maintain that stem cell research has incredible potential for research into

Diana Preston, 40

Living with Multiple Sclerosis

I'm 40 years old and I have a 17 year old daughter and have been married for 22 years. I was diagnosed with MS when I was 33. I work as a legal assistant and absolutely love my job. Thanks to my incredibly supportive and accommodating employer, I've been able to keep working from home despite my disease. Three years ago, I stopped driving and now I use either a scooter or a wheelchair to get around.

I have rapidly-worsening secondary progressive MS and I am considered a non-responder by many to most drugs, both approved for MS and for other illnesses. I was on two different types of chemotherapy in the past and I didn't respond to those drugs either. However, I am about to go on a very controversial new drug called Tysabri that was just re-approved by the FDA. after it was pulled off the market because of patient deaths. Even with its FDA approval, it is estimated that 1 in 1500 people will die from taking the drug.

I take it one day at a time, but I am essentially being forced to go on a drug that risks my life because I have no other options — there is nothing else out there for me. I have been following the stem cell story vigilantly, hoping that somehow scientific barriers will be broken and a treatment for my disease can be found. When I see how our federal government has trillions of dollars in deficits when we aren't taking care of things here at home like research and finding cures for diseases like mine, I just think that something has got to give.

Rhode Island has always been a rebel of sorts, kind of democratic and working for the people, and I really hope that Rhode Island will set the pace for the stem cell discussion so that a breakthrough can be made.

My Take

Elizabeth Morancy

Executive Director of the Alzheimer's Association, Rhode Island Chapter

"The Alzheimer's Association's goal is to eradicate Alzheimer's through the advancement of research. We therefore support any legitimate scientific avenue that offers the potential to advance this goal within appropriate boundaries... In keeping with this goal, the Alzheimer's Association opposes any restriction or limitation on human stem cell research, provided that the appropriate scientific review, and ethical and oversight guidelines are in place."

early human development, drug testing, regenerative cell-based therapies, and gene control and therapy.[15]

Embryonic stem cell research creates opportunities for scientists to study the development of the human body from the earliest stages of development. Scientists are researching what causes embryonic stem cells to differentiate, as well as what can go wrong along the way. This research can be instrumental in coming up with new therapies to prevent birth defects and disease.[16]

Stem cell research can also be an important aid to testing the safety and effectiveness of new drugs in more reliable ways. Although the science has not yet reached this point, researchers project that differentiation of stem cells into specific cell types could potentially allow tests of different drugs to be compared across identical cell lines. For example, if researchers wanted to test a new heart medicine, they could potentially manipulate stem cells to create lines of human cardiac cells, and then conduct the tests on these lines. This would give the scientists absolutely identical lines upon which to test safety, dosage, and effectiveness, and would allow the scientists to determine many of the effects of the medicine before testing it on humans. This would be very similar to the way cancer drugs are now tested on lines of cancer cells, but it would be much more flexible in its applications.[17]

Stem cells have the potential to differentiate into a wide range of cell types through the expression of different genes. Stem cell researchers are looking at ways to regulate how genes are expressed in stem cells that function abnormally and can sometimes cause cancer. This gene regulation has the potential to be used as a therapy to limit the growth of cancerous cells in some cases.[18]

Perhaps the most exciting potential in stem cell research is in developing cell based therapies that could regenerate diseased or destroyed tissue. Many scientists think that it may one day be possible to grow stem cells in a laboratory, force them to differentiate into specific cell types, and grow human tissue that can then be implanted into patients. For example, scientists may at some point be able to produce heart muscle cells in the lab that can be transplanted into a patient with heart disease. Other potential applications include the regeneration of damaged spinal and brain cells for treatment of spinal and nervous system injuries as well as neurological diseases such as Parkinson's and Alzheimer's.[19]

Although many of the potential stem cell therapies are still in the research phase, treatments using the stem cells in bone marrow and cord blood are currently available. These types of treatments do not rely on the manipulation of stem cells in the lab, but are effective simply due to the unique properties of stem cells.

One stem cell treatment that is currently being utilized is bone marrow transplantation. In this type of treatment, stem cells are replaced through transplantation in patients whose own stem cells have been destroyed by chemotherapy or radiation treatment. In order to do a bone marrow transplant, hematopoietic (blood cell producing) stem cells are collected from a matching donor, usually from the marrow of a large bone such as the pelvis, and transplanted into the recipient. Stem cells from cord blood can also be used for this purpose.

G. Where is stem cell research taking place?

The science of stem cell research is taking place at research institutions across the nation, even in states that do not have dedicated funding. It is important to realize, however, that as with any type of scientific research, the science very much follows the money. Therefore much of the stem cell research in states that do not have direct state funding for the research is being done on adult stem cells using NIH grants, as well as embryonic stem cell research using NIH-approved stem cell lines. Some examples of strong stem cell research programs at states that do not have direct funding include: the Pittsburgh Development Center of Magee, the University of Min-

nesota Stem Cell Institute, the Tulane University Center for Gene Therapy, and the Harvard Stem Cell Institute (which was started before Massachusetts began funding stem cell research).[20] In addition to federal funding, corporations with a vested interest, such as pharmaceutical companies, are funding university projects as well as their own research. As states begin to infuse large amounts of funding into stem cell research, it will become harder for research centers in states that do not have such programs to compete.

It is also important to note that in addition to the state, federal, and corporate funding of stem cell research, there is also a significant amount of private non-profit funding for the research. The Starr Foundation is providing $50 million over three years for human embryonic stem cell research at three New York City medical institutions. The University of California, Los Angeles established its Institute for Stem Cell Biology and Medicine with $20 million in funding in 2005, and Stanford University announcing the creation of $120 million Institute for Cancer/Stem Cell Biology and Medicine in 2002. Additionally, former Intel CEO Andy Grove gave the University of California, San Francisco a grant of $5 million to start its Developmental and Stem Cell Biology Program; an anonymous donor gave Johns Hopkins University in Baltimore a $58.5 million gift to launch an Institute for Cell Engineering; the University of Minnesota has set up a Stem Cell Institute with a $15 million capital grant; and a grateful patient pledged $25 million over the next ten years to finance stem cell research at the University of Texas Health Science Center in Houston.[21]

My Take

Congressman Patrick Kennedy

"So many Rhode Island families need real progress in the area of stem cell research. As state policy makers and health advocates continue the dialogue about the future of stem cell research in Rhode Island, I will continue to fight in Washington for federal funding of all stem cell research."

H. Issues surrounding stem cell research

While research into the medical therapeutic uses of adult stem cells and cord blood stem cells evokes little ethical debate, the use of embryonic stem cells for research purposes has given rise to some degree of controversy. Much of the controversy surrounds the fact that the collection of embryonic stem cells necessary for research results in the destruction of human embryos.

Some opponents of embryonic stem cell research maintain that human life begins when an egg cell is fertilized by a sperm cell, resulting in the creation of a zygote. Their position is that from this point forward, destruction of the embryo is not ethical. For example, the position of the organization Focus on the Family is, "In order to isolate and culture embryonic stem cells, a living, human embryo must be killed. It is never morally or ethically justifiable to kill one human being in order to benefit another. By requiring the destruction of embryos—the tiniest human beings—embryonic stem cell research violates the medical ethic, 'Do No Harm.'"[22] Individuals who hold this position often maintain that there is no clear line that separates an embryo from a human, and therefore any destruction of a post-zygote shows lack of respect for the value of human life.

Opponents of embryonic stem cell research also sometimes maintain that there is limited utility to the science behind the work. They maintain that other types of research, such as adult stem cell research and cord blood stem cell research, have greater potential for therapeutic uses than embryonic stem cell research. They also ascertain that the potential for therapies coming from embryonic stem cell research has been overstated, and question whether cures arising from this type of research will ever come about.

Supporters of embryonic stem cell research point out that embryonic stem cell research is done primarily on embryos remaining after *in vitro* fertilization treatments. These embryos, it is maintained, are slated to be destroyed or permanently stored. They state that instead of being wasted, these embryos can be used to further scientific study and potentially help cure human diseases and afflictions. They also point out that the blastocysts used are a group of undifferentiated cells, and in the course of normal development are a full eight weeks from any sort of brain function. Most supporters of embryonic stem cell research do not argue that the blastocysts lack value, but rather that the value they add by potentially being a part of curing diseases is greater than the value they would add were they to be destroyed or perpetually frozen. In the words of former Republican Senator John Danforth, "It is not evident to many of us that cells in a petri dish are equivalent to identifiable people suffering from terrible diseases. I

am and have always been pro-life. But the only explanation for legislators comparing cells in a petri dish to babies in the womb is the extension of religious doctrine into statutory law."[23]

In response to the argument that embryonic stem cell research is not the most productive form of stem cell research, supporters point to scientists who say otherwise. Many scientists are of the opinion that embryonic stem cells have the greatest potential for therapies because of their faster rate of division, as well as their plasticity (ability to differentiate into any kind of cell). Supporters of embryonic stem cell research also maintain that decisions about where to dedicate scientific resources should be left up to scientists and not governmental policymakers. It is important to note, however, that the work being done on embryonic stem cells is very much in the research phase, and has not been developed into clinical treatments.

My Take

Representative Eileen Naughton

"I'm working on public cord blood and regenerative medicine policy and programs in Rhode Island. Public cord blood is derived from the umbilical cord blood after the baby is born. Cord blood contains life-saving stem cells to all ethnic groups. Public cord blood is not controversial. Cord blood collection and use is supported by everyone. Right now, more than 1,000 Rhode Islanders do not have access to stem cell treatment because they do not have a bone marrow match available. That means they are not receiving life saving treatment.

"The promise of regenerative medicine provides tremendous hope to us all in understanding debilitating diseases in order to prevent, treat, and cure them. In Rhode Island, the public and private higher education, hospitals, and research institutions are a vibrant part of the state's economy and provide a robust opportunity for advanced research and ethical implementation of regenerative medicine. These institutions and the growing biotechnology industry will be a key component of the Rhode Island economy that provides jobs. Peer review together with public oversight will provide life -saving therapies while being grounded in thorough ethical concerns. Regenerative medicine inventions are in use, saving lives, e.g., skin replacement for wound healing, and an anticancer agent to combat a form of brain cancer."

Section II

Research Funding

A. Federal stem cell activity

When the discovery of human embryonic stem cells was announced in 1998, the Clinton administration formed a National Bioethics Advisory Commission to look into federal funding of research involving human embryos. One of the key questions for the panel was whether embryonic stem cell research would violate a federal law known as the Dickey Amendment that, as part of the annual Health and Human Services appropriation bill, outlaws federal funding of research that results in the destruction of human embryos.[24]

Based on the recommendations of the commission, in 1999 the Clinton administration decided that embryonic stem cell research did not violate the Dickey Amendment as long as the research did not itself cause the destruction of the embryo. This was based on the idea that it would be permissible to spend federal funds on embryonic stem cell research as long as the stem cells were collected using private funds. The 1999 Department of Health and Human Services decision clarified that federally funded research could be done (once stem cells were collected without the use of federal funds) because they determined that stem cells do not meet the statutory definition of an embryo in the Dickey Amendment.[25] Once the administration decided that embryonic stem cell research did not violate the Dickey Amendment, the Health and Human Services agency issued new guidelines in 2001 regarding embryonic stem cell research that effectively allowed the research under certain conditions. When President Bush came into office in 2001, the new guidelines were placed on hold pending further study.

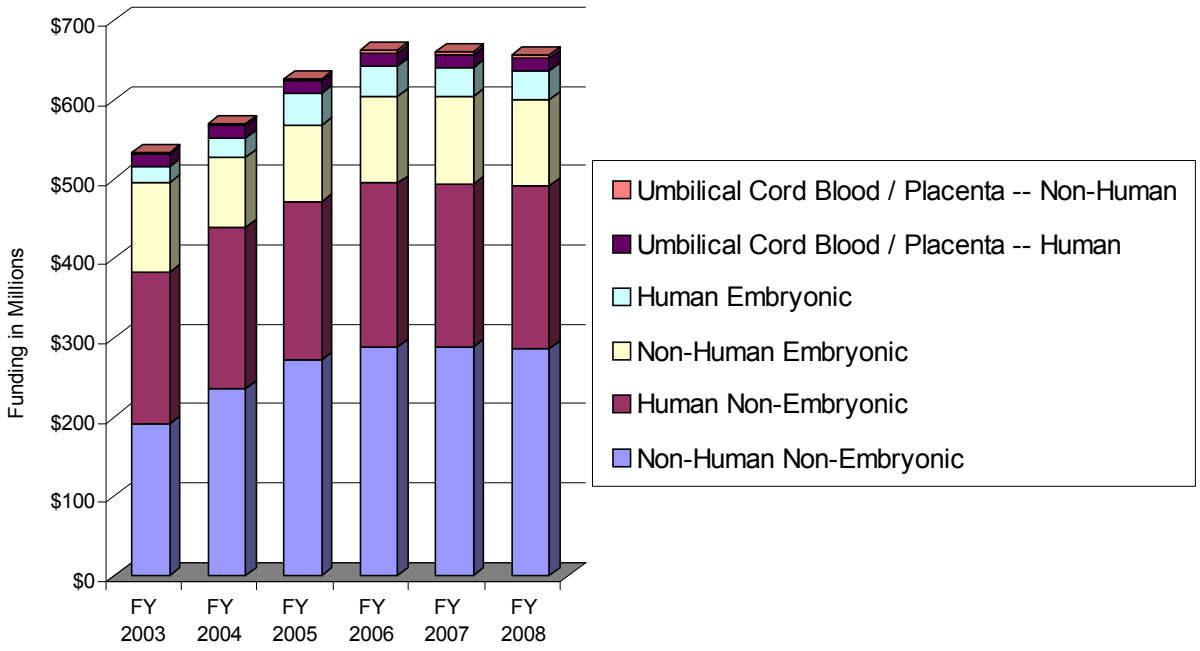
In August 2001, President Bush announced the first federal funding for stem cell research, but expressly limited the use of federal funding to conduct research on stem cell lines already then in existence. President Bush's rationale was that federal funding should be limited to those embryos for which "the life and death decision has already been made."[26] The Bush administration's ruling in 2001 was based on their interpretation of whether stem cells are embryos as defined by the Dickey Amendment. While the Clinton administration interpreted the Dickey Amendment definition of embryo as <u>not</u> including stem cells, the Bush administration has taken a different position. A paper released in 2003 by the President's Council on Bioethics explained that this position was the President's way of balancing his position that the destruction of embryos is morally wrong with the knowledge that embryonic stem cell research has the potential to save lives.[27]

Over the course of that year's legislative session, various bills were introduced in Congress either attempting to loosen stem cell research guidelines or attempting to outlaw forms of embryonic stem cell research. None of the bills passed either chamber. As of the latest available data, there are 22 stem cell lines that federally funded researchers are permitted to use under the Bush administration's 2001 ruling.[28]

In the 2005 legislative session, 15 bills were introduced in Congress relating in some way to stem cell research. In May 2005, the House of Representatives voted 238-194 in favor of H.R. 810 to allow federal funding of research using embryos left over from *in vitro* fertility treatments, regardless of when the lines were created. In July 2006, the Senate passed H.R. 810 63-37, and the next day President Bush vetoed it.

On January 11, 2007, the House of Representatives passed H.R. 3, the Stem Cell Research Enhancement Act of 2007, 253-174. This bill directs the Department of Health and Human Services and the National Institute of Health to expand funding of embryonic stem cell research to stem cell lines created after August 2001. The bill stipulates that research would only be eligible for federal funding if the embryos were originally created for reproductive purposes and discarded by the individual seeking the fertility treatment, and written consent was provided by the donor. The President has promised to veto the bill should it come to his desk.

NIH Stem Cell Funding [29]



Mary Burgess

My Daughter Emily Suffers From Type I Diabetes

On March 13, 2004, my daughter Emily was diagnosed with Type I diabetes. On that day her life and the lives of our whole family changed dramatically. Everything we do, every decision we make, every plan we make seems to revolve around Emily's illness. She is not able to go anywhere without there being safeguards in place. Will someone be able to help her if she needs it? Does she have her juice box, instant glucose, emergency plan, contact numbers, and blood sugar monitor? These are things I, as her mother, worry about every time she is away from me. Consequently, Emily is not able to attend birthday parties, visit or go out with friends from school, or go to sleepovers unless I am able to be with her. Every piece of food she eats needs to be addressed: how many carbs are in it, how much insulin does she need to cover it, will she be having activity that will burn some of it off? We also document everything: food, insulin doses, activity, blood sugar readings.

Six months after she was diagnosed, Emily began to administer her own insulin injections, 5-6 per day, and she continued to do this until October of 2006. At this time she went on an insulin pump. This has improved her life. She is able to be more flexible with her schedule, does not have to take along insulin and needles everywhere she goes, and no longer needs daily injections. However, it is not without stress. The pump needs to be changed every two days, and although it claims to be virtually pain free, it is not. When we go any distance we need to take a back up pump and insulin in case something happens to the pump. She still needs to test her blood sugar 6-8 times a day. Emily is a very active girl, plays soccer, basketball, softball, roller blades. Every time she engages in activity I worry that the tubing from the pump may get knocked out of place, and it often does. When this happens sometimes her blood sugar skyrockets and she becomes very ill, with stomach pain, chills, etc., before we realize the pump is no longer working.

Emily is a very sweet, happy, and brave girl. She has many friends who are great about helping her with the challenges she faces every day. At school

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she has two "buddies" who go everywhere with her, since it is never safe for her to be alone.

As her mother, I worry about her future. Will she have problems when she gets older, with her vision, kidney, liver, etc.? Will she be able to go away to college? Will she always be able to find people and friends in her life who will be willing to support her? Will she be able to have children, and if so, will she pass her disease on to them?

Before the last presidential election, our family talked a great deal about the importance of stem cell research and that if it was to move ahead Kerry would need to be elected. The day after the election when Emily, who was in grade 3 at the time, found out Bush had been re-elected, she cried. It is very frustrating to know that such great strides can be made to help Emily and so many others, and research is not able to move ahead because of the views of a few people.

In 2006, the National Institutes of Health funded $643 million in total stem cell research. Of this total, $206 million went toward human non-embryonic stem cell research, $38 million toward human embryonic stem cell research, and $399 million toward non-human stem cell research.[30] NIH funds would become available for research on many more embryonic stem cell lines should H.R. 3 pass into law. In March 2007, in a break from official administration policy, NIH Director Dr. Elias A. Zerhouni stated that he supports a policy that would better serve science by allowing researchers access to new stem cell lines.[31]

The role of advocacy organizations

While the debate about federal funding for embryonic stem cell research has been ongoing, many national advocacy organizations have become active in pressing for increased federal support for stem cell research. The primary mission of many national advocacy organizations is finding a cure for various diseases and conditions, such as Parkinson's and Alzheimer's disease. Some organizations, such as the Coalition for Advancement of Medical Research (CAMR), focus on the promise of stem cell research more broadly rather than with a focus on a specific disease or therapy. CAMR has been a leader in federal-level advocacy for a national approach to advancing stem cell research. These organizations are usually formed by a coalition of people living with disease or injury, family members of people affected by disease or injury, and members of the medical and scientific communities that have a professional interest in putting their research knowledge to work to fight for a cure to a particular disease. Most of these advocacy organiza-

tions also have a grassroots aspect to them in which members travel to Washington to advocate for increased research funding or changes in federal legislation.

What ties many of these advocacy organizations together is their dedication to promoting the potential of stem cell research to cure diseases and alleviate suffering. As the stem cell research debate has heightened, these organizations have focused their advocacy efforts heavily on legislation allowing for federal funding of embryonic stem cell research, particularly in the wake of President Bush's initial veto. Since the passage of H.R. 3 in January 2007, these organizations have been lobbying legislators and encouraging their membership to do the same. While most national advocacy organizations have maintained a focus on the federal level, some of these organizations also provide information and resources such as scientific experts to inform state level initiatives to fund stem cell research.

In addition to advocacy organizations pushing for increased funding of stem cell research, there are also organizations that oppose embryonic stem cell research. Many of these organizations are very supportive of adult stem cell research, but maintain that the government should not fund embryonic stem cell research. Some organizations, such as Focus on the Family, oppose embryonic stem cell research because of their broader concerns about any medical procedure that they define as compromising embryos.

B. State activity

Regulation of stem cell research has been ceded to state legislatures and private funders by the logjam at the federal level. States that have started the process of funding embryonic stem cell research take into account ethical considerations by reviewing grant applications and funding recipients. States formalize the review process through institutional review boards (IRBs) or embryonic stem cell review oversight (ESCRO) organizations. Some policy-makers and researchers have expressed concerns about the adverse impact that the fragmentation of different standards in different states may have on research. The National Academies of Science have published voluntary ethical and scientific guidelines for stem cell research that have been adopted by many researchers and universities, but in the absence of a uniform national policy, different state standards will remain a concern.[32]

However, because federal funding of embryonic stem cell research is limited to existing lines, a number of states have taken the initiative over the past few years to provide funding for this new area of research on their own.

This has created an arms race of sorts, in which many states feel that as other states fund stem cell research, they have no choice but to fund research as well or face the prospect of a flight of biotech researchers and companies from their state. The importance of biotech as an area of economic development for many states has also contributed to this dynamic with states competing to attract and hold research entities and the spin-off companies that are associated with geographically-concentrated research activities.

There are two dominant models that states granting direct funding for stem cell research have for the disbursement of funds. They have either set up a state-level stem cell institute with a related research fund, or they have set up a research fund by itself. Often stem cell institutes are linked closely to institutions of higher education within the respective states. States that have less money to put into infrastructure, such as Maryland, Connecticut, and Washington, tend to direct their money toward direct grants for research projects keeping the hope that the grants will be leveraged with private funds to have a greater impact. States that have thus far invested the most money into the funding of stem cell research, such as California, Massachusetts, and New Jersey, have put money into creating research facilities and building infrastructure as well as making direct grants to researchers.

There are four different funding sources that the states have tapped for their stem cell research programs. These are: bond sales, tobacco settlement money, legislative appropriations, and expenditures from the executive budget. The biggest state funded initiatives, such as those in California, New Jersey, and the proposed New York fund, use bond sales as their primary source of funding. A more controversial form of funding is through the executive budget, as was done in Wisconsin and Illinois, as this funding is not subject to the legislative process.

The vast majority of states that fund stem cell research have used legislation as the tool through which their initiatives are enacted. California went through the ballot initiative process, while Illinois and Wisconsin went the route of executive order as discussed above. In Missouri, a 2006 ballot initiative that specifically authorizes embryonic stem cell research was successful; however, it does not include a funding mechanism or governance structure.

Some states that have enacted stem cell research programs have had some issues with implementation. Some states, such as California, have been criticized for having a grant award process that is seen by some as not fully transparent. Other states, such as Massachusetts, have not had the full

support of the executive branch for the initiative, while states like Wisconsin have had executive support, but have encountered resistance from the legislature. Some states have also encountered legal challenges to many of the programs that they are attempting to put into place, most of them resting on the technical aspects of the individual laws and not specifically on their funding of research.

Below is a state-by-state summary of major stem cell funding initiatives. All information is current as of April 2007. Within each category, states are listed in alphabetical order, not by the size or breadth of their respective initiatives.

States with Stem Cell Research Funding

State	Funds Appropriated	State-level Institute Created?	Executive, Legislative, or Ballot Initiative?	Year in which initiative passed	Type of research being funded
California	$3 billion over ten years	Yes	Ballot	2004	Embryonic, adult
Connecticut	$100 million over 10 years	No	Legislative	2005	Embryonic, adult
Illinois	$15 million*	Yes	Executive	2005	Embryonic, adult
Indiana	$50 thousand*	Yes	Legislative	2005	Adult
Maryland	$15 million*	No	Legislative	2006	Embryonic, adult
Massachusetts	$12.5 million*	Yes	Legislative	2005	Embryonic, adult
New Jersey	$281 million*	Yes	Legislative	2004, 2006	Embryonic, adult
Ohio	$27.4 million*	Yes	Legislative	2003, 2006	Adult
Washington	$350 million over ten years	No	Legislative	2005	Not specified
Wisconsin	$55 million*, $440 million proposed over multiple years	Yes	Executive	2006	Embryonic, adult

**One time expenditure*

States Proposing Stem Cell Research Funding

State	Funds Appropriated	State-level Institute Created?	Executive, Legislative, or ballot initiative?	Year in which initiative passed	Type of research being funded
Iowa	$12.5 million proposed*	Proposed	Proposal before legislature	N/A	Embryonic, adult
New Mexico	$6 million proposed*	Proposed	Legislative	N/A	Embryonic, adult
New York	$2 billion over ten years proposed	No	Legislative	N/A	Embryonic, adult

**One time expenditure*

Other States Activities

State	Funds Appropriated	State-level Institute Created?	Executive, Legislative, or ballot initiative?	Year in which initiative passed	Type of research being funded
Florida	None	No	Groups are attempting to place initiative on ballot	N/A	Embryonic, adult
Virginia	None appropriated as of yet	No	Legislative	2005	Adult

Enacted Stem Cell Funding

1. California

On November 2, 2004, 59% of California voters approved Proposition 71, the ballot initiative authorizing stem cell research and funding in their state.[33]

The success of the ballot initiative resulted in a constitutional change that created the California Institute for Regenerative Medicine (CIRM), organized its governance, and provided for the issuance of $3 billion in bonds over ten years to fund both the institute and stem cell research grants.

a. Law

The CIRM was formed by Proposition 71 with the following purposes:

> (a) To make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the cure for, and/or substantial mitigation of, major diseases, injuries, and orphan diseases.
>
> (b) To support all stages of the process of developing cures, from laboratory research through successful clinical trials.
>
> (c) To establish the appropriate regulatory standards and oversight bodies for research and facilities development.

Proposition 71 called for the CIRM to be governed by an Independent Citizen's Oversight Committee (ICOC), made up of 29 members appointed by California's universities and public officials. Information regarding the membership of the oversight committee can be found in Appendix I.

The ICOC chooses from among its members a chair and vice chair. It also sets guidelines for the disbursement of bond money, makes grants to researchers and organizations, organizes working subgroups, and has oversight power over day to day operations of the institute.[34]

b. Funding

Proposition 71 provided for the sale by the state of $3 billion in bonds over ten years. The law stipulates that no more than $350 million in bonds be sold in any given year, and caps the amount allowed to be spent on administrative and capital expenses.

The law guides the CIRM to make grants that give priority to stem cell research that has the greatest potential to directly lead to therapies and cures. It also directs the CIRM to give priority to research that would be denied funding under federal stem cell guidelines. The law stipulates that the ICOC come up with guidelines to ensure that the state of California benefits from patents, royalties, and licenses that result from the state-funded research, while also ensuring that the medical research is not hindered by cumbersome intellectual property agreements.

Faced with a legal challenge that precluded them from issuing bonds at an acceptable interest rate, the CIRM has only been able thus far to make grants of $12.1 million to one hundred and seventy aspiring researchers.

The CIRM was sued by two organizations shortly after the passage of Proposition 71. One organization, the California Family Bioethics Council, sued on the grounds that there was a conflict of interest within the CIRM. They asserted that it was a violation of state law to allow representatives from institutions of higher education to serve on a board that could award grants to their respective universities. There was also a suit brought by the People's Advocate and National Tax Limitation Foundation on the grounds that many of the board members were not authorized within state law to spend state money. In February 2007, a state appeals court upheld the CIRM, but this ruling is expected to be appealed to the California Supreme Court.[35] With the legal challenge still underway, Governor Schwarzenegger agreed to loan the CIRM $150 million from the state's general funds. The institute has also managed to raise another $31 million from philanthropic organizations in the form of notes in anticipation of bonds. This $181 million is now ready to be disbursed, and on January 11, 2007, the CIRM announced that it is soliciting research proposals for $48.5 million in new funds.[36] On February 16, 2007, the institute announced that it had awarded nearly $45 million in research grants to twenty state universities and nonprofit research laboratories. The institute also announced that another twenty-nine grants worth $75 million were awarded in March 2007.

c. Implementation

After a vigorous competition between ten California cities, the ICOC selected San Francisco to house its headquarters, based on the city's proposal that provided $18 million in donated benefits and services to CIRM, including: 20,000 square feet of office space, rent-free for a decade; 6,000 hotel rooms over 10 years (2,000 free rooms with the balance discounted); and seven conference venues of 300-50,000 seats free for ten years.[37] The ICOC has also selected members for its working groups, and has staffed the CIRM.

The California stem cell program has been criticized on a number of fronts beyond the general opposition to embryonic stem cell research. It has been argued that a $3 billion dollar expenditure is excessive given California's fragile economy and current debt situation. Critics maintain that the wording in the statute guiding the institute to ensure that the state is compensated if research pays off is vague, and not easily enforceable given established academic intellectual property policies. The CIRM has also been criticized for not fully disclosing information about grant applications, as well as for their process for awarding the grants.

My Take

Dr. David A. Ames

Clinical Assistant Professor of Community Health at the Warren Alpert Medical School at Brown University

"I have been interested in medical ethics since the early 1970s and have realized its importance as a discipline for how we respond to those who suffer from diseases and chronic conditions having little or no viable therapeutic remedy. In my work as an ordained minister in the Episcopal Church, I have been a pastor to many individuals and families who suffer from chronic illness and debilitating diseases. We need to work together in responding to the medical, spiritual, and psychological needs of patients and their families utilizing the best practices of every professional caregiver. With advances in our knowledge of human genetics, we are now at a critical juncture for developing research that could yield new therapies and better health for many people.

"With respect to stem cells, I am convinced that adult and embryonic stem cells hold tremendous promise for addressing many conditions that impair health and well-being. Couples having embryos that are products from *in vitro* fertilization that are not going to be implanted for reproductive purposes should be encouraged to donate those embryos for stem cell research. Appropriate federal and state guidelines that support both human tissue and embryonic stem cell research could assure the highest ethical standards. It is important that therapies resulting from research be made available to those in need, and that clinical trials follow existing established procedures."

My Take

Representative Ray Sullivan

"We all know someone who could benefit from the hope of stem cell research. Whether it is a family member or a friend, we know someone for whom the therapies that may result in the future from stem cell research conducted today may be life-saving or life-improving. Stem cell research is already saving the lives of leukemia patients. It is one of the most promising avenues for discoveries that could lead to treatments for Alzheimer's disease and paralysis. As Rhode Island continues to grow its biotechnology sector we must not miss the opportunity to encourage responsible and ethical research that may lead to the next life-saving breakthrough of tomorrow."

2. Connecticut

On June 15, 2005, Governor Jodi Rell signed into law "An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings." This act permits stem cell research, creates governance bodies to oversee the research, and provides a revenue stream for stem cell research funding that totals $100 million over ten years.

a. Law

The law stipulates that doctors providing *in vitro* fertilization treatment must provide patients with information about donating unused eggs. It allows for stem cell research to be conducted in the state provided that the researcher provides documentation as to the origin of the stem cell lines and is approved by an institutional review committee.

The Commissioner of Public Health is charged with enforcing the provisions of the law, and implementation is placed within the Department of Public Health's Office of Research and Development. The law also authorized the creation of two committees, the Stem Cell Research Advisory Committee (SCRAC), and the Stem Cell Research Peer Review Committee (SCRPRC). Information about the membership of the advisory committee can be found in Appendix II.

The SCRAC is charged with four specific duties. It is directed to develop a donated funds program to

encourage development in funds other than state appropriations for stem cell research, to examine ways to improve stem cell research in the state, to establish and administer a stem cell research grant program, and to monitor and oversee grant recipients. The law also charges Connecticut Innovations, Inc., with staffing the council and providing administrative support.[38]

b. Review committee

The SCRPRC is made up of five members appointed by the Commissioner of Public Health and serving four year terms. All members must have knowledge and practical experience in stem cell research. The duty of this committee is to review all applications for grants, and make recommendations to the Commissioner and the SCRAC. The SCRPRC is charged with drafting guidelines for the scoring and rating of applications.

c. Funding

For funding purposes, the law creates a Stem Cell Research Fund, a separate account within the general fund. It appropriates $20 million from the general fund to begin stem cell funding, and provides $10 million a year from 2008 through 2015 from the Tobacco Settlement Fund, for a total of $100 million over ten years. The Commissioner of Public Health makes all grants, but is guided and advised by the two committees.

d. Implementation

In May 2006, requests for proposals went out for the first round of funding, and seventy applications were received. On November 21, 2006, the SCRAC directed the award of $19.78 million in stem cell research funds to twenty-one research proposals, 95% of which went to researchers at Yale or the University of Connecticut.[39]

3. Illinois

On July 12, 2005, Illinois Governor Rod Blagojevich signed an executive order creating the Illinois Regenerative Medicine Institute (IRMI). The executive order placed the institute under the Department of Public Health, and directed the department to set aside $10 million in initial grants.[40]

a. Executive Order

The executive order directed the institute to "study therapies, protocols, medical procedures, possible cures for, and potential mitigations of major

diseases, injuries, and orphan diseases; to support all stages of the process of developing cures from laboratory research through successful clinical trials, and to establish the appropriate regulatory standards for research and facilities development." It also set aside funds in the executive budget to fund the research.[41]

b. Grant Application Review Panel

The Department of Public Health created a panel consisting of two bioethicists and six medical professionals with expertise in stem cell research to review grant applications. The institute received twenty-four applications for stem cell grants, and in April 2006, awarded ten grants worth a total of $10 million.[42]

My Take

Bill Koconis

Executive Director of the Leukemia and Lymphoma Society, Rhode Island Chapter

"The Society's mission — to find cures for blood cancers — is dependent on broad and open-ended scientific inquiry. No one knows where the next breakthrough in blood cancer research might occur. Adult stem cells are integral to our research program because their use is a principal approach to therapy in leukemia, lymphoma, and myeloma. Adult stem cell therapy, although greatly improved, carries a significant rate of mortality and morbidity, especially in older patients. Embryonic stem cell research can accomplish several goals central to the Society's mission: (1) we can learn how undifferentiated cells form mature functional cells and (2) we can develop improved methods of transplantation that reduce mortality and morbidity from the procedure to near zero. The differentiation process is disordered in the development of leukemia, lymphoma, and myeloma. New transplantation methods could revolutionize treatment of these diseases."

c. Funding

In addition to the first round of funding provided for in the executive order, Governor Blagojevich ordered that another $5 million be used from the Department of Public Health's administrative budget for stem cell research grants in July 2006. This money was awarded in August 2006 to seven research projects.[43]

Governor Blagojevich proposed $100 million in additional financing in his proposed FY07 budget,[44] but the funds were not approved by the legislature. In December 2006, a bipartisan group of legislators proposed a more modest $25 million appropriation to be funded using tobacco settlement funds, but it is unclear whether that will move forward.[45] Though the IRMI is still in existence, it has expended its total appropriation and has received no additional funds.

4. Indiana

In July 2005, the State of Indiana passed into law a bill that banned many types of embryonic stem cell research, and provided for the creation of an adult stem cell center at the University of Indiana.[46]

The law bans human cloning, and restricts the use of embryonic stem cells to those from lines permissible under federal law. It allows fetal research to be conducted only on miscarried or stillborn fetuses, but not aborted fetuses.

The law also permits the board of trustees of the University of Indiana to create an adult stem cell research center, to be placed under the administration of the School of Medicine. The law directs that the dean of the School of Medicine appoint a director for the center, and the board of trustees oversee all income.

According to the statute, the purpose of the center is to "conduct a thorough and comprehensive needs assessment of the state of science of adult stem cell research, and to develop strategies to move Indiana University into the forefront of the nation in its capacity to attract and retain adult stem cell researchers."

The 2005 Indiana state budget appropriated $50,000 to establish the adult stem cell research center. No further appropriations have been made or proposed since.

5. Maryland

On April 6, 2006, Governor Bob Ehrlich signed into law the "Maryland Stem Cell Research Act of 2006." This act created the Stem Cell Research Fund, and authorized the Stem Cell Research Commission to oversee and make grants from the fund. The bill authorized the legislature to appropriate money, and $15 million was appropriated for FY07 (beginning July 1, 2006).

a. Law

The law stipulates that the Maryland Stem Cell Research Fund be managed and administered by the Maryland Technology Development Corporation (TEDCO). It also authorizes an oversight commission called the Stem Cell Commission. This commission is directed to establish an independent scientific peer review committee composed of stem cell experts. This committee is charged with coming up with procedures for choosing grant recipients, as well as reviewing all applications and making recommendations to the commission.[47] Information about the membership of the oversight commission can be found in Appendix IV.

b. Implementation

In November 2006, the commission made a public request for applications for the first round of funding.[48] The applications were due on January 8, 2007, and awards were expected to be made by March 2007. The commission announced that there will be two types of grants. One of the awards is worth up to $200,000 over two years and earmarked for exploratory ventures by those new to the stem cell field. The other award is worth up to $1.5 million over three years, and is set aside for projects that have data supporting their validity.

On January 18, 2007, Governor Martin O'Malley released his proposed Fiscal year 2008 budget, which included $25 million in additional funding for the research fund.[49]

6. Massachusetts

In May 2005, the Massachusetts General Court passed "An Act Relative to Enhancing Regenerative Medicine in the Commonwealth," and successfully overrode then-Governor Mitt Romney's veto. This act permits embryonic stem cell research in Massachusetts, and directs the Commonwealth to take steps to spur research and development in the area of biotechnology and stem cell research.

Jean Vient

Former President of the Rhode Island Chapter of the American Parkinson's Disease Association

My daughter was 40 years old when she was diagnosed with Parkinson's Disease. It was such a heartache to my daughter and her husband and their 8 children. At the time, their youngest child was 8 years old and their oldest was 22 years old. I had always heard that Parkinson's disease was an old person's disease, so I was very surprised with her diagnosis.

Parkinson's was an unfamiliar disease to me and I didn't know anyone else with it. My daughter decided she would learn all she could about the disease through her doctors and the Rhode Island Chapter of the American Parkinson's Disease Association.

I quickly learned that Parkinson's is not an old person's disease, that every day Parkinson's strikes younger and younger persons just like my daughter. Most importantly, I also learned that there is no cure for Parkinson's disease. Funding is vital to finding a cure. My family and I participate in several events every year to raise money for Parkinson's disease research. For the past several years, we have walked in walkathons in Rhode Island and New York City — the RI Chapter/APDA holds its annual walkathon in September in Goddard Park and the Parkinson's Unity Walk is held every spring in Central Park in New York City. The Unity Walk has raised over $7 million in 12 years, all funds being allocated toward Parkinson's disease research!

I will continue to raise money for Parkinson's disease research. However, I realize that government has to untie the hands of the research scientists by opening up the stem cells lines. This is vital to research, to finding the cure for those already diagnosed and those who have yet to be diagnosed with Parkinson's disease.

a. Law

Among other initiatives, the Massachusetts stem cell act authorizes the creation of an umbilical cord blood bank at the University of Massachusetts, and stipulates that the bank would accept public donations and allow for researchers to access the blood for research purposes. It also creates a Public Institutional Review Board, in order that small research institutions or individuals have access to a board that can apply regulatory standards to their research.

The law stipulates that the Department of Public Health enforce the provisions of the chapter, under the guidance of the biomedical research advisory council. The Department of Public Health is also charged with certifying all institutions engaged in stem cell research in the state.[50]

b. Advisory Council

The law creates a biomedical research advisory council, the purpose of which is to make recommendations to the governor and legislature regarding biotech and stem cell research, as well as to oversee the implementation of the bill. Information about the membership of this board can be found in Appendix IIIA.

c. Funding

In 2006, the legislature made two direct appropriations for stem cell research in the Commonwealth, and again overrode then-Governor Romney's veto. The first law, Chapter 122, 7100-0550, appropriated $2.5 million for a biomedical institute at the University of Massachusetts. The law stipulates that $1.5 million of the appropriation go toward the purchase of equipment, and $1 million go toward the creation of a stem cell biology core to serve as a resource and registry for all newly established stem cell lines, and provide researchers in the state access to them.[51]

The second law, Chapter 123, Section 23I, created the Massachusetts Life Sciences Center (MLSC) to be overseen by the Department of Public Health and the biomedical research advisory council, and made an appropriation of $10 million to the Life Sciences Investment Fund.[52]

d. Board of Directors

The law directs that the MLSC be placed in the Office of Economic Development, and be governed by a five-member board of directions. Information

about the membership of the board of directors can be found in Appendix IIIB.

The law gives the MLSC a number of specific powers relating to stem cell research in Massachusetts. The purpose of the granted powers is to create an entity that coordinates all stem cell research and biotechnology in the state. Among other powers, it is granted the ability to borrow money and issue bonds, enter into agreements with public and private entities that deal with biotechnology and stem cell research, and buy real estate.

The MLSC is also granted administrative power over the Massachusetts Life Science Investment Fund. The purpose of the fund is to finance the administrative costs of the MLSC, and invest in biotechnology and stem cell research in Massachusetts. The law directs that the money go toward stimulating research in the life sciences by leveraging public and private financing, making targeted investments in life science research, offering matching grants to research institutions, and providing bridge financing to institutions in anticipation of future funding.

e. Implementation

Though the laws provide the mechanisms for stem cell funding in Massachusetts, there have been a number of barriers to implementation. These lie both in the regulations put into place by the Department of Public Health, and with the appointments made to the MLSC Board of Directors by outgoing Governor Romney, who had unsuccessfully vetoed the legislative enactments that created the initiative and the board.

In August 2006, the Massachusetts Public Health Council adopted regulations on embryonic stem cell research that Harvard and other research institutions maintain could expose scientists to criminal prosecution for conducting certain research activities. The controversy lies in the regulations' prohibition of the creation of a fertilized embryo with the intent of "using" it for research, while the law prohibits the creation of embryos with the purpose of "donating" the embryo. This means that the regulations ban some of the research activities that are permitted in the law.[53] The new governor, Deval Patrick, has directed his administration to reexamine the regulations.

The MLSC board is controlled by the governor, and as Governor Romney was leaving office, the board voted to appoint Aaron D'Elia to the post of Executive Director over the objection of Governor-elect Patrick. D'Elia has no experience in biology or science, has a bachelor's degree in history, and was previously an assistant secretary in the office of the budget planner. Like Romney, D'Elia is against human cloning for research purposes, a re-

search option legal under Massachusetts law. D'Elia was given a one-year contract, and Governor Patrick does not have the power to remove him without cause.[54]

7. New Jersey

In January 2004, then-Governor James McGreevey signed into law legislation legalizing stem cell research in the state of New Jersey. The law stipulates that individuals or institutions conducting such research must be reviewed by an institutional review board.[55]

My Story

Gary Brandyberry, 50

Living with Multiple Sclerosis

I've had MS for about 9 years and I am now 100% in a wheelchair. I'm 50 years old and retired in January from the Home Depot, which was always willing to change things at work to make sure that I was able to keep on working despite my disease.

MS is a rollercoaster, and when you get to a certain point, medicine doesn't help anymore. I need new wiring, and stem cells offer the only hope to grow that new wiring that I and other sufferers from MS need. There is a real possibility that we could regain some function because of stem cell research if researchers were able to turn myelin into useful spinal cord cells so that I could get that regeneration back and have those connections re-made. What a difference it would make in our lives.

I can't even imagine if I could walk again. You have no idea the barriers that are out there when you are in a wheelchair. For as much as our society has done, the everyday barriers are unbelievable. Stem cell research could be a lifesaver for me.

In 2005, the state budget contained an appropriation for $6.5 million to open the New Jersey Stem Cell Institute (NJSCI).[56] This money from the state, along with $3.5 million in private funds, allowed the institute to begin work and to start making grants. In 2006, the state appropriations for the institute totaled $5.5 million,[57] and the 2007 budget includes an appropriation for an additional $5.5 million.[58]

a. The Institute

The NJSCI is a public-private partnership that came into being through a memorandum of understanding between Rutgers University and the University of Medicine and Dentistry of New Jersey—Robert Wood Johnson Medical School. The memorandum of understanding directs that the institute be created to carry out stem cell research, and bring together public and private capital to build on the existing strengths of both universities in this area. The institute is governed by an eleven-member board of managers that oversees operations.[59] Information about the membership of this board can be found in Appendix V.

b. Direct Grants

The state also set up a grant program in 2005 through the State Commission on Science and Technology. The Commission controls the grant-giving process, and sets up both a scientific review board made up of stem cell experts, and an ethics review board chaired by the President Emeritus of Princeton University.[60]

My Take

Representative Arthur Handy

"I've worked in the public health field with groups like the American Lung Association, and I have seen the need for solutions to the tragic health problems of those devastated by illnesses for which there are no cures or even effective treatments. As an elected official, I have also heard from those who are directly affected by the lack of effective treatments for some of the most serious diseases. So I understand and appreciate the very real need for research into the potential of stem cell based therapies.

"For me, the most important role I play as a legislator is to work to create policies that improve our residents' lives by protecting their health and also strengthening the state's economy by creating a positive environment for technologies like stem cell therapy to flourish."

The grant program awarded $5 million in December 2005 to seventeen research proposals, and the money was appropriated to the Science and Technology Commission in Fiscal Year 2006.[61] Governor Jon Corzine announced in December 2006 that the 2007 grant program will total $10 million. Seven million dollars will be earmarked for core facilities grants in the amount of $1 to $3 million per grant, and $3 million will go to individual research grants of up to $300,000 per grant.[62]

Government officials in New Jersey are currently in negotiation regarding plans to place a question on the November 2007 ballot asking voters to approve an additional $230 million for stem cell research funding.

c. Capital Funding

In addition to the Stem Cell Institute and the Grant program, in December 2006, legislation was enacted that allows for the issuing of $270 million in bonds for major capital construction projects that will benefit stem cell research. This includes $150 million to fund the building of facilities for the Stem Cell Institute in New Brunswick, and $50 million to the fund capital costs of stem cell research facilities in Newark. It also includes $50 million to fund the capital costs of biomedical facilities, $10 million to fund the capital cost of blood collection facilities, and $10 million to fund the capital costs of cancer research facilities.[63]

8. Ohio

In 2003, Ohio created the Center for Stem Cell and Regenerative Medicine with a $19.4 million grant made to fund adult stem cell research in the state.[64] In 2006, Ohio's Biomedical Research and Commercialization Program made an additional award of $8 million to continue funding the research at the center.

In June 2005, Governor Bob Taft vetoed legislation outlawing state funding of embryonic stem cell research, but simultaneously issued an executive order mandating that all state-funded embryonic stem cell research comply with federal standards.[65]

9. Washington

In May 2005, Governor Christine Gregoire signed into law a bill establishing the Life Sciences Discovery Fund (LSDF), and providing for its funding. The fund is not specifically targeted toward stem cell research, and to date there are no public plans for stem cell research grants.

a. Law

The LSDF was created to improve the life sciences research environment in Washington and to foster improved health care outcomes for the state. The law directs the fund to make grants to projects that plan on leveraging those funds to receive money from other sources.[66]

b. Funding

The LSDF is funded through a $350 million allocation over ten years from the Washington tobacco settlement fund. These funds will not be made available until 2008. It is also authorized to receive private donations, and on January 18, 2007, it was announced that the fund received $3 million in contributions from philanthropic organizations to jumpstart the grant program.[67]

10. Wisconsin

Wisconsin has been at the forefront of stem cell research since University of Wisconsin Professor James Thomson became the first researcher to successfully isolate human stem cells in 1998. The Wisconsin Alumni Research Foundation holds the patents to six federally approved stem cell lines, and in 2006, the National Institute of Health chose Wisconsin to be the home of the National Stem Cell Bank. This bank serves as the distribution center for the twenty-one lines of embryonic stem cells that are eligible for federal funds, as well as providing technical support for researchers using the lines.[68]

a. Executive Order

Governor Jim Doyle has been extremely supportive of state funding for stem cell research and in April 2006 released an executive order laying out his goal of attracting 10% of the stem cell research market to Wisconsin by 2015.[69]

To this end, the governor has announced plans for a ten-year $750 million public/private partnership for biotechnology research.[70] Of that, $490 million is proposed to come from state funding, with the remainder to come from the private sector. Governor Doyle has already authorized $50 million in state funding to start the initiative. This state money will combine with $50 million from the Wisconsin Alumni Research Foundation and $50 million from philanthropists John and Tashia Morgridge to start building the Wisconsin Institutes for Discovery at the University of Wisconsin at Madison.[71]

b. Institutes for Discovery

The Wisconsin Institutes for Discovery will be made up of two separate yet complementary research institutions. One will be called the Wisconsin Institute for Discovery, and will be a public institute for biotech research. The other will be called the Morgridge Institute for Discovery, and will be a private institute that is able to interact with drug companies in a way that the public institute would not be allowed to. The focus of the institutes will be biotechnology in general, but stem cell research is sure to be a major focus. The plan is for the institutes to be open for research around late 2009.

My Story

Rhonda O'Donnell, 44

Living with Multiple Sclerosis

I'm 44 years old and I was diagnosed with MS twelve years ago and have been an active member of the local MS community here in Rhode Island ever since. Most recently, I traveled to Washington for the National MS Society's annual public policy conference to meet with other MS advocates and lobby our Rhode Island delegation about a number of issues, including stem cell research. I've also been a local self-help group leader for 10 years.

I think the writing is on the wall that down the road, stem cell research will be the key to curing diseases and making them more manageable for people to live with. With MS, your body attacks itself and with every person, the disease is extremely variable as it progresses. While I have problems walking and often use a scooter or a walker, another person with MS may not have any problems using their legs. It's really scary because my disease is always progressing and I just never know what's going to happen.

Stem cell research could make people's quality of life so much better. If gene therapy could be used to replace diseased cells in our bodies, it would be incredible — not only for MSers, but for people with spinal cord injuries and many other conditions. I'm extremely fortunate to have the support of my family in living with MS but some people aren't so lucky.

c. Stem Cell Grants

The governor also signed an executive order directing $5 million from the Department of Commerce to recruit and retain companies involved in stem cell research. These funds have been distributed in the form of direct grants and loans to stem cell companies in Wisconsin.[72] Since these funds are an executive expenditure, Governor Doyle has control of the direction of the funding. In September 2006, the governor also announced plans to award grants of $250,000 to stem cell companies relocating to or expanding in the state.[73]

In May 2006, the University of Wisconsin at Madison invited researchers to submit proposals for $3 million in seed grants. The purpose of the program is to jumpstart research projects that may eventually find a home at the Institutes for Discovery.[74]

Additionally, the governor plans to add a stem cell development specialist to the Wisconsin Entrepreneur's Network, the state's small business development agency, to support companies that wish to start up in or relocate to the state.

Proposed Stem Cell Funding

11. Iowa

In January 2007, newly elected Governor Chet Culver announced that he would be asking the legislature to lift an existing ban on embryonic stem cell research in the state. He also proposed a state appropriation of $12.5 million to construct a Center for Regenerative Medicine to be located at the University of Iowa.[75]

12. New Mexico

As a part of his Fiscal Year 2008 budget, Governor Bill Richardson has proposed a plan to use state funds to support embryonic stem cell research. His proposal includes $3.8 million in one time funding to build a stem cell facility, and $2.2 million in annual funding for the facility. The plan has encountered strong opposition from the Catholic Church in the state.[76]

13. New York

Despite being home to leading medical centers and researchers, efforts to bring stem cell funding to New York have consistently been stalled in the legislature. On January 12, 2007, newly elected Governor Eliot Spitzer

My Take

Senator Rhoda Perry

"For several years, I have been following the national debate on stem cell research. I was motivated to introduce legislation to specifically enable stem cell research in Rhode Island after speaking with researchers at Brown University. They enhanced my understanding that having enabling legislation for stem cell research in Rhode Island would help advance both university level research and the growth of the emerging biomedical research industry in Rhode Island.

"My underlying goal in introducing enabling legislation in this area of course has been to bring hope to people who are in such extremely difficult circumstances: those who are affected by paralysis, Alzheimer's, dementia, Parkinson's, MS and other diseases or injuries."

called for passage of a $2 billion, ten year bond for research and development, with half of it to be set aside for stem cell research. In his State of the State address, Spitzer proposed creating a Stem Cell and Innovation Fund, led by Lieutenant Governor David Paterson.[77] Although specific plans have yet to be released, the proposed budget, released in January 2007, includes $100 million for stem cell research, and a bond proposal of $2.1 billion over eleven years.[78] This proposal has encountered some resistance in the legislature from those who argue that it contains economic development "pork" disguised as stem cell funding.[79] These charges stem from the fact that the proposal does not limit the money to stem cell research, but would allow it to be available to ''new agribusiness,'' ''security technologies,'' and nanotechnology.[80]

Other State Activity

14. Florida

Stem cell research advocates in Florida are gearing up to place initiatives on the state ballot in 2008, and are concurrently pursuing a legislative avenue to funding.

Former Attorney General (and now Governor) Charlie Crist asked the state Supreme Court to determine whether two competing initiatives could be placed on the ballot in 2008. One initiative would require the state to spend $200 million on stem cell research over ten years, while the other would ban state funding of embryonic stem cell research.[81]

In January 2007, Florida Representative Franklin Sands filed a bill that would achieve the same goals as the proposed ballot initiative favoring stem cell research.[82] This bill would also require the formation of a Stem Cell Research Advisory Council and Biomedical Ethics Advisory Council to regulate research procedures and enforce ethical guidelines. The governor supports the bill, but legislative leaders are against it, and a similar bill failed to reach the floor last session.

15. Virginia

In March 2005, Virginia enacted two laws relating to stem cell research. The first law created the Christopher Reeve Stem Cell Research Fund. The law stipulates that none of the money appropriated by the state be used for embryonic stem cell research. It also directs that the fund be administered by the Commonwealth Health Research Board. In January 2007, a bill was filed in the Virginia legislature to amend the law to allow embryonic stem cell research.[83]

The second law created a joint commission to study the medical, ethical, and scientific policy implications of stem cell research.[84] Information about the membership of the committee can be found in Appendix VI. The committee has published recommendations that state funding be directed toward cord blood research, and not toward embryonic stem cell research.[84]

C. Initiatives encountering road blocks

In addition to the fifteen states listed above, government officials in many other states have tried and met severe challenges to enacting legislation permitting or funding stem cell research.

Nine states have encountered problems attempting to pass legislation that specifically permits embryonic stem cell research: Minnesota, Pennsylvania, Rhode Island, Tennessee, Hawaii, Nebraska, South Carolina, Texas, and Missouri.

Four states have had difficulties passing legislation that would establish stem cell research study commissions: Arizona, Hawaii, North Carolina, and Missouri.

Additionally, nine states have found resistance to funding stem cell research through legislation: Hawaii, New Mexico, Minnesota, Nebraska, North Carolina, Texas, Florida, Missouri, and South Dakota.

My Take

Kathy Mechnig

President of the Rhode Island Chapter of the National Multiple Sclerosis Society

"Multiple Sclerosis is considered an autoimmune disease where the body attacks itself, resulting in damage to the nervous system. MS can cause paralysis, blindness, cognitive dysfunction, mobility impairment, and many other serious symptoms. To find new ways to prevent, slow the progression of, or repair the devastating effects of MS, the National Multiple Sclerosis Society supports the conduct of scientifically meritorious medical research, including research using human cells, in accordance with federal, state, and local laws and with adherence to the strictest ethical and procedural guidelines.

"Research using all types of stem cells, both adult and embryonic, holds great promise, potential, and hope for people affected by MS. There is a high likelihood that stem cell research will improve our understanding of the MS disease process and lead to new pathways for therapeutic intervention. Stem cells could have the potential to be used to protect and rebuild tissues that are damaged by MS and to deliver molecules that foster repair or protect vulnerable tissues from further injury. Stem cells can also be cultivated in lab dishes where they can be used to find new drugs and to discover new genes and molecules with the potential to stop MS or repair its damage. Stem cells created with the DNA of persons with MS may help answer questions about the cause of MS and may help us model and treat MS once the underlying cause of MS is better understood.

"We believe that all promising avenues that could lead to the cure or prevention of MS or relieve its most devastating symptoms by repairing MS damage must be explored."

Section III

The Rhode Island Stem Cell Landscape

The present challenges and opportunities regarding stem cell research in Rhode Island cannot be examined in a vacuum. It is important to look at what has already gone on in the state, both in terms of legislation and actual research.

A. Laws and legislation

There is no Rhode Island law that specifically restricts the use of human adult or embryonic stem cells for research purposes. The Rhode Island law that does restrict some uses of human cells explicitly permits research as long as the research is not for the purposes of cloning an entire human being—which is not part of stem cell research.[86]

Starting in 2003 and continuing every year thereafter, bills were introduced that would have explicitly allowed all forms of stem cell research and created a procedure for unused embryos as a result of *in vitro* fertilization treatments to be donated for the purpose of stem cell research. These bills

Dr. Peter Quesenberry
Stem Cell Researcher,
Rhode Island Hospital

My Take

"New developments in stem cell biology have opened up tremendous opportunities for treatment of a number of devastating diseases characterized by tissue destruction. The NIH is now failing to fund critical research in this regard, especially the translation of these findings to patient treatment. A critical mass of stem cell biologists, clinical investigators, and stem cell transplanters is now present in Rhode Island. A comprehensive center supporting both basic and clinical work would move this field forward and offer the availability of stem cell clinical trials to citizens of Rhode Island. The work will not move at an adequate pace without such a center."

were sponsored in the House by Representative Edith Ajello, and in the Senate by Senator Rhoda Perry. A 2007 version of the bill, 2007 H-6082, is currently under consideration by the House of Representatives.

In 2006, a resolution sponsored by Representative Eileen Naughton was passed, creating a special House commission to promote and develop a nationally recognized cord blood program for the future of disease management in Rhode Island. That commission began meeting in February of 2007. In 2007, a resolution sponsored by Representative Naughton was introduced to create the Rhode Island House of Representatives Regenerative Medicine and Research Advisory Study Commission. The resolution, 2007 H-5672, is currently under consideration by the House of Representatives.

B. Current research in Rhode Island

There is a significant amount of stem cell research taking place in Rhode Island, primarily with adult stem cells. According to Dr. Peter Quesenberry of Rhode Island Hospital, much of the stem cell work in the state is being done at Rhode Island Hospital, Brown University, and Miriam Hospital.

Dr. Quesenberry notes that the research in Rhode Island ranges from his team's work on stem cell phenotypes and general foundations of stem cell research to work at other facilities that have to do with using marrow cells in the treatment of various diseases. One example of such work is the research being done by Dr. Mehrdad Abedi at Roger Williams Medical Center. Dr. Abedi is looking for ways to manipulate bone marrow cells so that they turn into muscle cells. He says that if successful, this could potentially be the basis for a cure to diseases such as muscular dystrophy.

Dr. Quesenberry estimates that there are roughly ten to fifteen specific areas of investigation in Rhode Island regarding stem cell research, with well over thirty researchers working on the projects.

C. The biotech/biomedical economy in Rhode Island

Rhode Island is currently a very strong player in the biotechnology sector, in terms of both research and industry. The state currently ranks 8th in NIH funding[87] per capita,[88] receiving over $123 million for scientific research. About two thirds of this total is directed toward Brown University, Miriam Hospital, and Rhode Island Hospital.[89] Biotechnology is also an extremely important part of the Rhode Island industrial economy, employing over 4,700 individuals, and providing over $270 million in direct wages.[90] State funding assistance to the biotech sector has the potential to be com-

pounded by the federal dollars that state researchers would be in a better position to receive by virtue of a state investment.

Section IV

Economic Opportunities for Stem Cell Research in Rhode Island

Without federal funding dominating the research and leveling the playing field, states are viewing stem cell research funding as an economic development tool. Rhode Island has the potential to use an advance in stem cell research funding as a way to grow its economy. By using state funding for research as a lure for biotech and pharmaceutical companies, Rhode Island may be able to increase its biotech economy and create high-paying jobs.

States have also created a process for making a return on stem cell research investments through revenue-sharing. States are staking a claim to a part of the potential profits that may be realized through patents and intellectual property derived from state-funded research, acting more like active investors than traditional research funding sources. Rhode Island has the potential to develop research funding that may provide a return on the state's investment.

In the economic development arms race that has developed surrounding stem cell research, states are engaging in escalating attempts to offer enticements to stem cell researchers and companies in an attempt either to lure them from other states, or to retain researchers already located in their own state.

In such a competitive environment, finding a place for Rhode Island will pose a challenge, but one which does not appear to be insurmountable given some of Rhode Island's positive attributes. Rhode Island possesses a number of characteristics that give it an edge when it comes to biotech research in general and stem cell research in particular. These characteristics include: small size and resulting agility, an extremely advantageous geographic location, and a concentration of research-oriented institutions of higher education.

Differing state standards regarding the regulation of stem cell research fragment researchers, stifling collaboration across state lines and potentially hindering research advances. Connecticut has proposed an interstate alliance to examine the standardization of stem cell research regulation across state lines. If Rhode Island can collaborate with Connecticut and Massachusetts to create regional standards for stem cell research, the po-

My Take

Dr. Michael Lysaght

Director of the Center for Biomedical Engineering at Brown University

"The more scientists learn about stem cells, the more remarkable they seem to be. They avoid the lure of terminal specialization, which is the fate of more prosaic cells. Embryonic stem cells contains the full architecture that we become. Even in adults these advantaged biologic forms, are able to regenerate and replace the more functional cells which make up tissue and organs.

"The 'adult vs. embryonic' debate sets up a false dichotomy. Both forms are likely to aid in the ongoing quest to find therapies which prolong human life and alleviate human suffering. It is difficult to see how any entity can claim breadth and leadership potential in 21st century life-sciences without a strong and unfettered program to bring stem cells into clinical practice."

tential exists to create a hub for stem cell research, combining funding capacity for greater advances.

Section V

Key Policy Questions

When analyzing the key stem cell research policy questions Rhode Island faces, one must keep in mind that Rhode Island cannot outspend larger states like California, New York, or Massachusetts. To expand stem cell research in Rhode Island, the state must consider finding a way to offer advantages that these bigger states cannot, as well as identifying particular niche areas of research to which the existing resources and research institutions of the state are uniquely suited.

The Rhode Island House of Representatives is in the process of establishing a Regenerative Medicine and Research Advisory Study Commission. This group will be charged with looking into some of the opportunities and challenges for Rhode Island in the area of stem cell research. Below are some questions that will need to be examined by any group interested in looking into the challenges and opportunities specific to Rhode Island.

Policy Question:

Should Rhode Island enact a program that uses public funds, alone or in combination with private funds, to provide direct grants to stem cell researchers and companies?

Even though Rhode Island is not positioned to provide the largest dollar amount or most numerous grants, it is still possible that establishing a pool of state funds to stimulate research might be advantageous.

Policy Considerations:

- Is a state-funded direct grant program necessary to prevent stem cell researchers and companies that are currently in the state from leaving?
- Are state-funded grants necessary to recruit researchers and companies from other states?
- Can Rhode Island institute a grant funds program of sufficient scope to be meaningful and to have the desired effect of stimulating new and additional stem cell research efforts in Rhode Island?
- What returns would the state see on this investment?
- What are Rhode Island's policy goals for such an investment — solely the expansion of research efforts, solely the creation of new companies and laboratories at the research institutions as a means of economic development, or some combination of these two goals?

Policy Question:

Should Rhode Island establish and fund a statewide stem cell institute?

One of the ways that Rhode Island could potentially both leverage its current resources, as well as capitalize on our small size, is through the formation of a statewide stem cell institute, like seven other states, to coordinate and stimulate the stem cell research activities.

Policy Considerations:

- To what extent could such an institute bring together and leverage the resources we currently have in the state?
- What effect would this have on recruitment and retention of stem cell researchers and companies?
- Has the creation of a central institute been important to the success of stem cell initiatives in other states that are further along than Rhode Island or can the functions of an institute be undertaken by the Department of Health or another existing entity?

Policy Question:
Should Rhode Island enact legislation to explicitly permit various types of stem cell research, including but not limited to embryonic stem cell research?

With so many states with clear laws and funding welcoming stem cell researchers and companies, states in which the laws either are unclear or restrict the legality of certain forms of research may be at a disadvantage.

Policy Considerations:
•What advantages would be gained through changes to existing Rhode Island law?
•What form should enabling legislation take?
•What ethical considerations should be reflected in such legislation and how should governance structures reflect the need to address ethical considerations?
•How can legislation clarify the public policy of the state regarding each of the three primary areas of stem cell research: adult stem cell research, cord blood research, and embryonic stem cell research?
•Does Rhode Island want to identify by statute particular areas of research that are supported by the state?

Policy Question:
Should Rhode Island offer financial incentives such as tax credits or tax free zones to stem cell researchers?

Policy Considerations:
•What potential do these incentives have to aid in the recruitment and retention of stem cell researchers and companies?
•What would be the cost of such programs?
•What is the potential for financial return to the state?

Policy Question:
What role should Rhode Island play in cord blood research?

Cord blood research is the most advanced of all areas of stem cell research with regard to current therapies. Patients around the country are already being treated for diseases like leukemia and sickle cell anemia through cord blood therapies.

Policy Considerations:

- Should the state establish a cord blood bank?
- What form should a cord blood bank take, if the state were to establish one?
- Should the state establish a cord blood research center?
- Should the state institute legislation that would result in increased donation of cord blood, such as laws encouraging or requiring doctors to explain cord blood donation to pregnant women and new parents?
- Should the state institute policies, through statute or otherwise, that enable the public donation of cord blood by Rhode Island parents as part of a national network for the public donation of cord blood without a cord blood bank in Rhode Island?

Conclusion

Rhode Island stands ready to begin discovering its role for future stem cell research — to chart a course toward relieving the pain and suffering of Rhode Islanders, while also creating a new economic engine. The potential for social and economic benefit for Rhode Island citizens from vigorous basic and applied research in this area cannot be overestimated. With research already underway, and with barriers to federal funding for some aspects of research, the time is right for the Ocean State to pursue the discussion of its future in stem cell research and other regenerative medicine. Rhode Island is fortunate to have the substantial intellectual and institutional resources of our major research universities and hospitals, and Rhode Islanders have already been actively examining how best to advance the human and economic potential of biomedical research for their fellow citizens. Now is the time to define how stem cell research and regenerative medicine should advance locally.

Elected and appointed officials, researchers and policy-makers, the business community, investors, advocacy groups, and citizens must engage in a rigorous dialogue about what the future for stem cell research should be in Rhode Island. The role of government in supporting these efforts must also be examined. While some other states have already launched initiatives, Rhode Island still has an opportunity to carve out a particular area or areas of specialization within the research fields related to stem cells.

Will Rhode Island be the home to a stem cell institute? Should Rhode Island establish a way for families to publicly donate cord blood? Should state and local government put incentives in place to stimulate growth in this sector to achieve the reduction of human suffering and support economic growth for the state? Rhode Islanders have an historic opportunity to work together to answer these questions, evaluate the successes and challenges that other states have faced, and chart the course for a healthier and stronger state.

Appendix I

California's ICOC Membership

The members of the ICOC hold either 6 or 8 year terms, and are appointed as follows:

(1) The chancellors of the University of California at San Francisco, Davis, San Diego, Los Angeles, and Irvine, shall each appoint an executive officer from his or her campus.
(2) The governor, the lieutenant governor, the treasurer, and the controller shall each appoint an executive officer from the following three categories:
    (A) A California university, excluding the five campuses of the University of California described in paragraph (1) that has demonstrated success and leadership in stem cell research and that has:
        (i) A nationally ranked research hospital and medical school; this criteria will apply to only two of the four appointments.
        (ii) A recent proven history of administering scientific and/or medical research grants and contracts in an average annual range exceeding one hundred million dollars ($100,000,000).
        (iii) A ranking, within the past five years, in the top 10 United States universities with the highest number of life science patents or that has research or clinical faculty who are members of the National Academy of Sciences.
    (B) A California nonprofit academic and research institution that is not a part of the University of California that has demonstrated success and leadership in stem cell research, and that has:
        (i) A nationally-ranked research hospital or that has research or clinical faculty who are members of the National Academy of Sciences.
        (ii) A proven history in the last five years of managing a research budget in the life sciences exceeding twenty million dollars ($20,000,000).
    (C) A California life science commercial entity that is not actively engaged in researching or developing therapies with pluripotent or progenitor stem cells, that has a background in implementing successful experimental medical therapies, and that has not been awarded, or applied for, funding by the institute at the time of appointment. A board member of that entity with a successful history of developing innovative medical therapies may be appointed in lieu of an executive officer.

(D) Only one member shall be appointed from a single university, institution, or entity. The executive officer of a California university, a nonprofit research institution or life science commercial entity, who is appointed as a member, may from time to time delegate those duties to an executive officer of the entity or to the dean of the medical school, if applicable.

(3) The governor, the lieutenant governor, the treasurer, and the controller shall appoint members from among California representatives of California regional, state, or national disease advocacy groups, as follows:

(A) The governor shall appoint two members, one from each of the following disease advocacy groups: spinal cord injury and Alzheimer's disease.

(B) The lieutenant governor shall appoint two members, one from each of the following disease advocacy groups: type II diabetes and multiple sclerosis or amyotrophic lateral sclerosis.

(C) The treasurer shall appoint two members, one from each of the following disease groups: type I diabetes and heart disease.

(D) The controller shall appoint two members, one from each of the following disease groups: cancer and Parkinson's disease.

(4) The speaker of the Assembly shall appoint a member from among California representatives of a California regional, state, or national mental health disease advocacy group.

(5) The president pro tempore of the Senate shall appoint a member from among California representatives of a California regional, state, or national HIV/AIDS disease advocacy group.

Appendix II

Connecticut Stem Cell Research Advisory Committee Membership

The Stem Cell Research Advisory Committee (SCRAC) is chaired by the Commissioner of Public Health. It has eight other members appointed as follows:

- Two by the governor
  - One active stem cell investigator
  - One person with a background in bioethics
- One by the president pro tempore of the Senate who has a background and experience in private sector stem cell research
- One by the speaker of the House of Representatives who has a background and experience in private sector stem cell research
- One by the majority leader of the Senate who has a background in academic stem cell research.
- One by the majority leader of the House who has a background in academic stem cell research.
- One by the minority leader of the Senate who has experience in private or public stem cell research
- One by the minority leader of the House who has experience in business or financial investments

Members serve four year terms, except for appointments by the governor and majority leaders, who serve two year terms.

Appendix III

A. Massachusetts Biomedical Research Advisory Council

The board consists of 15 members appointed to three year terms, of which:

Five are appointed by the governor
- Secretary of Health and Human Services, or his designee
- Commissioner of the Department of Public Health, or his designee
- An experienced scientist designated by the Dean of University of Massachusetts Medical School
- A licensed physician
- A medical ethicist, designated by Dean of University of Massachusetts Medical School

Four are appointed by the president of the Senate
- An experienced scientist
- A licensed physician
- A medical ethicist
- A member of Massachusetts bar with experience in biotechnology issues

One member appointed by senate minority leader
- A member of the public

Four appointed by the speaker of the House
- An experienced scientist
- A member of Massachusetts bar with experience in biotechnology issues
- A representative of the Biotechnology Center of Excellence Corporation
- An individual with an economic development background

One appointed by the minority leader of the house
- A member of the public

B. Massachusetts Life Sciences Center Board of Directors

The board, made up of members serving five year terms, consists of:
- The Secretary of Administration and Finance, or a designee
- The Director of Economic Development, or a designee
- The President of the University of Massachusetts, or his designee
- Two members appointed by Governor
  - One licensed physician
  - One CEO of a Massachusetts based life sciences corporation who is a member of the Massachusetts Biotechnology Council

Appendix IV

Maryland Stem Cell Commission

The Stem Cell Commission is a 15 member board whose members serve two terms and consists of:

- The attorney general, or designee
- Three patient advocates, one appointed by each of the following: the governor, the president of the Senate, and the speaker of the House of Delegates
- Three individuals with experience in biotechnology, one appointed by each of the following: the governor, the president of the Senate, and the speaker of the House of Delegates
- Two individuals who work as scientists for the University System of Maryland (USM) and do not engage in stem cell research, appointed by USM
- Two individuals who work as scientists for the Johns Hopkins University (JHU) and do not engage in stem cell research, appointed by JHU
- Two bioethicists, one appointed by USM and one by JHU
- Two individuals with expertise in the field of biomedical ethics as it relates to religion, appointed by the governor

The chair is chosen from among the members.

Appendix V

New Jersey Stem Cell Institute Board of Managers

The institute is governed by an eleven member board of managers that oversees operations. The Board of Managers includes:

- Executive Vice-President for Academic Affairs of Rutgers University
- Senior Vice President for Academic Affairs of University of Medicine and Dentistry of New Jersey
- Dean of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School
- Chief Operating Officer of Rutgers University
- One additional member appointed from each of the participating universities
- New Jersey Commissioner of Health and Senior Services
- Executive Director of the New Jersey Commission on Science and Technology
- One representative from the Office of the Governor of New Jersey
- Two public members appointed by the governor for three-year terms.

The leadership of the board alternates annually between the Senior Vice President for Academic Affairs of University of Medicine and Dentistry of New Jersey and the Executive Vice President of Rutgers University.

Appendix VI

Virginia Stem Cell Study Commission

The joint subcommittee shall have a total membership of 15 members that shall consist of eight legislative members and seven non-legislative citizen members. Members shall be appointed as follows:

- Five members of the House of Delegates to be appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates;
- Three members of the Senate to be appointed by the Senate Committee on Rules;
- One representative of the University of Virginia School of Medicine
- One representative of the Eastern Virginia Medical School,
- Two non-legislative citizen members at-large to be appointed by the Speaker of the House of Delegates;
- One representative of the Virginia Commonwealth University School of Medicine;
- Two non-legislative citizen members at-large to be appointed by the Senate Committee on Rules.

Non-legislative citizen members of the joint subcommittee shall be citizens of the Commonwealth of Virginia. The joint subcommittee shall elect a chairman and vice chairman from among its membership, who shall be members of the General Assembly.

Endnotes

1. Stem Cell Basics. In *Stem Cell Information*. National Institutes of Health, U.S. Department of Health and Human Services. 2006. 20 December 2006. <http://www.stemcells.nih.gov/info.basics/.com>.
2. ibid.
3. The Lasker Foundation *History of Stem Cell Research.* Lasker Medical Research Network. 2001. <http://www.laskerfoundation.org/rprimers/stemcell/history.html>.
4. ibid.
5. National Institute of Health-Stem Cell Information. National Institutes of Health, U.S. Department of Health and Human Services. 2006. 20 December 2006 <http://www.stemcells.nih.gov/info.basics/.com>.
6. The Century Foundation. Stem Cells and Public Policy. The Century Foundation Press: New York City. 2006.
7. Stem Cell Basics: What are adult stem cells?: In *Stem Cell Information*. National Institutes of Health, U.S. Department of Health and Human Services. 2006. 30 March 2007. <http://stemcells.nih.gov/info/basics/basics4>
8. National Institute of Health-Stem Cell Information. National Institutes of Health, U.S. Department of Health and Human Services. 2006. 20 December 2006 <http://www.stemcells.nih.gov/info.basics/.com>.
9. Johnson, Alissa. Stem Cells: *A Guide for Policymakers*. Denver: National Conference of State Legislatures, 2006
10. Wade, Nicholas. "Journal Clarifies Report On Stem Cell Finding". The New York Times. 23 November 2006. 1.
11. Elias, Paul. "Amniotic fluid yields stem cells"*. Harvard researches report.* The Boston Globe. January 7 2007. 1
12. National Cord Blood Program. 2003-2004. <http://www.nationalcordbloodprogram.org/about/program_overview.html>.
13. "CORD BLOOD BANKING FOR FUTURE TRANSPLANTATION NOT RECOMMENDED." American Academy of Pediatrics 6 July. 1999: 1.
14. "The Benefits of Cord Blood" State Legislatures. Feb. 2007
15. Stem Cell Basics: What are the potential uses of human stem cells and the obstacles that must be overcome before these potential uses will be realized?: In *Stem Cell Information.* National Institutes of Health, U.S. Department of Health and Human Services. 2006. 30 March 2007 http://stemcells.nih.gov/info/basics/basics6
16. ibid
17. ibid
18. Lin, Haifan. "Stem Cells, Small RNAs and Self-Renewal." StemCONN07. Hartford Hilton, Hartford, CT. 28 MAR 2007.
19. Stem Cell Basics: What are the potential uses of human stem cells and the obstacles that must be overcome before these potential uses will be realized?: In *Stem Cell Information.* National Institutes of Health, U.S. Department of Health and Human Services. 2006. 30 March 2007 http://stemcells.nih.gov/info/basics/basics6
20. In *Stem Cell Information* [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2006 [cited Monday, April 02, 2007] Available at <http://stemcells.nih.gov/research/educresearch>
21. Bailey, Ronald. "Do We Really Need the Feds?." Reason Magazine 24 AUG 2005 02 APR 2007 <http://www.reason.com/news/show/34993.html>.
22. "Stem Cell Research." Focus on the Family. Focus on the Family. 3 Apr 2007 <http://www.family.org/socialissues/A000000373.cfm>.
23. "What People are Saying." Alliance for Stem Cell Research. Alliance for Stem Cell

Research. 3 Apr 2007 <http://www.curesforcalifornia.com/page.php?id=115>.
24. Balanced Budget Downpayment Act, 1996, H.R. 2880, Public Law 104-99
25. National Bioethics Advisory Committee. Issues in Human Stem cell Research: *Executive Summary.* National Advisory Bioethics Advisory: 1999.
26. President George W. Bush. "President Discusses Stem Cell Research" The White House 9 Aug 2001.
27. "The Administration's Human Embryonic Stem Cell Research Funding Policy: Moral and Political Foundations by The President's Council on Bioethics", Sept. 2003, www.bioethics.gov/background/es_moralfoundations.html
28. In *Stem Cell.* National Institutes of Health, U.S. Department of Health and Human Services. 2007. 30 March 2007. <http://stemcells.nih.gov/info/faqs>
29. Ricardo Alonso-Zaldivar and Karen Kaplan. "Embryonic stem cell research gets surprise support." Los Angeles Times 20 March. 2007.< http://www.latimes.com/news/nationworld/nation/la-na-stemcell20mar20,1,6121617.story?track=rss&ctrack=1&cset=true>
30. National Institutes of Health. 2007. 5 Feb. 2007 <http://www.nih.gov/news/fundingresearchareas.htm>.
31. Ricardo Alonso-Zaldivar and Karen Kaplan. "Embryonic stem cell research gets surprise support." Los Angeles Times 20 March. 2007.< http://www.latimes.com/news/nationworld/nation/la-na-stemcell20mar20,1,6121617.story?track=rss&ctrack=1&cset=true>
32. "Guidelines for Human Embryonic Stem Cell Research" (2005, rev. 2007). The National Academies, <http:/books.nap.edu/openbook.php?isbn=0309096537>
33. CNN.com Election Results. 2005. 14 June. <http://www.cnn.com/ELECTION/2004/pages/results/states/CA/>
34. State of California Proposition 71, www.cirm.ca.gov/prop71/pdf/prop71.pdf
35. CBS5.com. 2007. 26 Feb. <http://cbs5.com/topstories/local_story_057195130.html>
36. http://www.cirm.ca.gov/. 2006.
37. Pagano, Nicole. "Stem Cell Agency Opens Doors in San Francisco." California Institute for Regenerative Medicine. 2006. 1 Nov. 2006. http://www.cirm.ca.gov/pressreleases/2005/11/11-01-05.asp
38. Connecticut Public Act No. 05-149: An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings, 2005, http://www.cga.ct.gov/2005/act/Pa/2005PA-00149-r00sb-00934-pa.htm
39. Connecticut Department of Health Office of Research and Development. State of Connecticut 2003-2004. <http://www.dph.state.ct.us/StemCell/Grants.htm>
40. Illinois Regenerative Medicine Institute. "GOVERNOR BLAGOJEVICH, COMPTROLLER HYNES ANNOUNCE $10 MILLION STEM CELL RESEARCH PROGRAM TO FUND MEDICAL CURES." News Release. 12 July 2005. <http://www.idph.state.il.us/irmi/news_071205.html>
41. Executive Order 2005-6 Creating the Illinois Regenerative Institute for Stem Cell Research, http://www.illinois.gov/Gov/pdfdocs/execorder2005-6.pdf
42. Illinois Regenerative Medicine Institute. "Gov. Blagojevich, Comptroller Hynes announce $10 million in state stem cell research grants." News Release. 24 April 2006. <http://www.idph.state.il.us/irmi/news_042406.html>
43. Illinois Regenerative Medicine Institute**.** "Gov. Blagojevich announces recipients of $5 million in new state stem cell research funding." News Release. 17 August 2006. <http://www.idph.state.il.us/irmi/news_081706.html>
44. State of Illinois FY 07 Budget
45. Yednak, Crystal. "Lawmakers Map New Stem-Cell Push" Chicago Tribune. 15 December 2005.

46. http://www.in.gov/legislative/bills/2005/SE/SE0268.1.html
47. Maryland Technology Development Corporation. <http://www.marylandtedco.org/_media/pdf/SCRF.pdf>
48. Crovo, Laura. "Maryland Technology Development Corporation." <http://www.marylandtedco.org/ media/pdf/StemCellsMDPubNoticeRFAs11-1-06-2.pdf>. 1 Nov 2006.
49. Green, Andrew. "O'Malley Seeks Increase in Stem Cell Funding" The Baltimore Sun 4, Apr. 2007
50. Chapter 27 of the Acts of 2005. <http://www.mass.gov/legis/laws/seslaw05/sl050027.htm>
51. Chapter 122 of the Acts of 2006. <http://www.mass.gov/legis/laws/seslaw06/sl1060122.htm>
52. Chapter 123 of the Acts of 2006. <http://www.mass.gov/legis/laws/seslaw06/sl1060123.htm>
53. Medical News Today. 2006. 4 Sep 2006. <http://medicalnewstoday.com/medicalnews.php?newsid=50911> and Massachusetts Stem Cell Regulations. 2006. 29 Aug 1006. <http://www.lawlib.state.ma.us/stemcellregs.html>
54. Estes, Andrea. "Patrick Objects as Romney Fills key Slot." Boston Globe 1 Dec 2006. 1.
55. New Jersey Senate Bill No. 1909, An Act concerning human stem cell research and supplementing Title26 of the Revised Statutes and Title 2C of the New Jersey Statutes, 2002
56. Department on the Treasury. P-392. <http://www.state.nj.us/treasury/omb/publications/05budget/pdf/82.pdf>
57. Department of the Treasury. P-390. <http://www.state.nj.us/treasury/omb/publications/06budget/pdf/82.pdf>
58. Department of the Treasury. P-402. <http://www.state.nj.us/treasury/omb/publications/07budget/pdf/82.pdf>
59. State of New Jersey Commission on Science and Technology. <http://nj.gov/scitech/stemcell/institute/memo.html>
60. State of New Jersey Commission on Science and Technology. <http://nj.gov/scitech/stemcell/grants/index.html>
61. State of New Jersey Commission on Science and Technology. <http://nj.gov/scitech/stemcell/grants/awardrecipients.html>
62. State of New Jersey Commission on Science and Technology. 2007. <http://nj.gov/scitech/pdf/stemcell/Stem%20Cell%20Application%20Guidelines%202007.pdf>
63. New Jersey Permanent Status Database. 2007. <http://lis.njleg.state.nj.us/cgi-bin/om_isapi.dll?clientID=21507607&Depth=2&depth=2&expandheadings=on&headingswithhits=on&hitsperheading=on&infobase=statutes.nfo&record={CEAA}&softpage=Doc_Frame_PG42>
64. The Center for Stem Cell and Regenerative Medicine. 2007. <http://ora.ra.cwru.edu/stemcellcenter/>
65. Medical News Today. 2005. 6 Jul. 2005. <http://www.medicalnewstoday.com/medicalnews.php?newsid=27024>
66. State of Washington Senate Bill 5581 - 2005-06: Establishing the life sciences discovery fund.
67. The Life Science Discovery Fund Authority. "Private donors partner for early launch of Life Sciences grant program" 18, Jan. 2007 <http://www.lsdfa.org/about/files/01-18-07_LSDF_press_release_final.pdf>
68. National Stem Cell Bank. <http://www.wicell.org/index.php?option=com_oscommerce&Itemid=130>

69. Doyle, Jim. "Executive Order 147." Office of the Governor Jim Doyle. 2007. 30 March 2007._____<http://www.wisgov.state.wi.us/journal_media_detail.asp?locid=19&prid=1943>
70. Devitt, Terry. "Wisconsin Poised to Invest $750 million in Biomedical Reasearch." Wisconsion: University of Wisconsin-Madison. 20 March 2004 <http://www.news.wisc.edu/10446.html>
71. University of Wisconsin-Madison. "Wisconsin Institutes for Discovery" 2007. 8 Feb 2007. <http://discovery.wisc.edu/qa.php>
72. Lupardus, Anne. "Governor Doyle Commits $5million to Recruit Stem Cell Companies." Office of the Governor Jim Doyle. 2006. 25 April 2006. <http://www.wisgov.state.wi.us/journal_media_detail.asp?locid=19&prid=1942>
73. Vigue, Carla. "Governor Doyle Announces Partnership to Recruit, Retain Stem Cell Companies." Office of theGovernor Jim Doyle. 2006. 28 Sep. 2006. <http://www.wisgov.state.wi.us/journal_media_detail.asp?locid=19&prid=2346>
74. University of Wisconsin-Madison. "35 Research Teams invited to Submit Proposals." 2007. 12 Feb. 2007. "http://discovery.wisc.edu/seedInvitees.php"
75. DesMoinesRegister.com editorials. "Repeal Iowa's limits on stem-cell research" Editorial. 30 Jan 2007.
76. Baker, Deborah. "Bishops Press Richardson to Drop Stem Cell Plan" Associated Press 26, Jan. 2007
77. Spitzer, Elliot. "One New York." <http://www.ny.gov/governor/keydocs/NYS-SoS-2007.pdf>
78. Building the New Economy. 2007-08. <http://publications.budget.state.ny.us/fy0708littlebook/EconomicDevelopment.html>
79. Hakim, Danny. "The Empire Zone; Spitzer's Stem Cell Plan May Not Steamroll Through The Assembly" The New York Times. 19 Feb. 2007, 1.
80. ibid
81. Dolinski, Catherine. "Florida's Stem Cell Division" --The Tampa Tribune 27 Nov. 2007
82. Florida House of Representatives. HB 555 Biomedical Research. 6 March 2006. <http://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=35058&BillText=HB+555&HouseChamber=H&SessionId=54&>
83. Virginia Acts of Assembly - H2256 -- An Act to amend the Code of Virginia by adding in Title 23 a chapter numbered 22.1, consisting of sections numbered 23-286.1 and 23-286.2, relating to the Christopher Reeve Stem Cell Research Fund, 2007
84. Virginia Acts of Assembly - S1194 -- An Act to amend the Code of Virginia by adding in Title 23 a chapter numbered 22.1, consisting of sections numbered 23-286.1 and 23-286.2, relating to the Christopher Reeve Stem Cell Research Fund, 2007
85. Associated Press. "Stem Cell Research May Be Replaces in Virginia" WTOP: Washington's News, Weather & Traffic. 17 Jan. 2006. <http://www.wtopnews.com/index.php?nid=25&sid=673773>
86. Rhode Island General Laws §23-16.4-1 et. seq.
87. NIH Awards by State of Recipient Institution, Fiscal Year 2005, http://grants1.nih.gov/grants/award/trends/states05.htm
88. U.S. Census Bureau National and State Population Estimates, Annual Population Estimates 2000 to 2006, http://www.census.gov/popest/states/NST-ann-est.html
89. National of Health Office of Extramural Research. 2007. 27 Feb 2007 <http://grants.nih.gov/grants/award/trends/State_Congressional/StateDetail.cfm?year=2005&state=RI>
90. RI Tech Collective BioGroup Report – Biotech in the Rhode Island Economy, 2006, http://biogroupri.org/ui/user/File/TEC_31_Textpages_FA.pdf

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